PATENT
Atty. Docket No.: Le A 35 010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Henning, *et al.*

SERIAL NO.: New filing

FILING DATE: herewith

TITLE: Method for Specifically Detecting Tumour Cells and Their Precursors in Uterine Cervical Smears by Simultaneously Measuring At Least 2 Different Molecular Markers

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PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This Preliminary Amendment is submitted in the above-captioned application. Please amend the application as follows:

In the Claims

Please amend claims 1-11 as shown in the attached sheets. A marked version of the claim set showing the changes made is also attached.

Remarks

By way of this Preliminary Amendment, claims 1-11 are pending. Claims 1-11 have been amended. These claim amendments are being made solely for purposes of placing the claims in a format appropriate for U.S. prosecution. No new matter was added by way of these claim amendments and additions.

More specifically, claims 3-11 are being amended to remove the improper multiple dependent claim format in compliance with 37 C.F.R. § 1.75(c). Applicants submit that all of these amendments do not change the scope of the claims as originally filed, because the amendments are being made solely to place the claims in a format appropriate for U.S. prosecution. Such amendments are therefore made to address formalities in the claim format and are not related to the patentability of the subject matter of the claims.

Conclusion

Applicants believe that the subject matter of the pending claims is patentable and that the instant application should accordingly be allowed. If the Examiner believes that a conversation with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned attorney at (203) 812-6540.

Respectfully submitted,

Dated: December 17, 2001

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Amended Claims (Attorney Docket No. Le A 35 010)

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1. (Amended) A method for detecting tumour cells and their precursors in uterine cervical smears by simultaneously detecting at least two molecular markers in a cell.

2. (Amended) The method according to Claim 1, further characterized in that the markers are selected from the group consisting of: tumour suppressor genes, apoptosis genes, proliferation genes, repair genes and viral genes.

3. (Amended) The method according to Claim 1, characterized in that at least one of the markers comprises her2/neu, p16, p53, MN, mdm-2, bcl-2, EGF receptor, and specific DNA from the HPV subtypes 6, 11, 16, 18, 30, 31, 33, 35, 45, 51 and 52.

4. (Amended) The method according to Claim 1, wherein the marker combinations comprise her2/neu with p16 or EGF-R with p16 or p53 with her2/neu or her2/neu with mdm-2 or bcl-2 with p16 or bcl-2 with her2/neu or p16 with p53.

5. (Amended) The method according to claim 1, further characterized in that 3 markers are detected.

6. (Amended) A kit for implementing the method according to Claim 1.

7. (Amended) The kit according to Claim 6, further characterized in that the reagents are antibodies or nucleic acids.

8. (Amended) The kit according to Claim 7, characterized in that the antibodies or nucleic acid probes are read directly or indirectly using fluorescent or chromogenic dye substances.

9. (Amended) The method according to Claim 1, characterized in that it enables abnormal cells to be detected in an automated manner, wherein at least two markers are detected and the signal intensities are combined and summated.

10. (Amended) The method according to Claim 9, characterized in that the automatic information processing is combined with a diagnostic expert system which enables the image information to be consolidated into a proposed diagnosis and, where appropriate, enables reflex testing to be carried out.

11. (Amended) The method according to Claim 1, wherein the method comprises fully automatic sample preparation, sample staining, sample reading and information processing or subprocesses which comprise at least two of the given subprocesses.

Amended Claims (Attorney Docket No. Le A 35 010)
Version with Markings to Show Changes to Claims

1. (Amended) A method for detecting tumour cells and their precursors in uterine cervical smears by simultaneously detecting at least two molecular markers in a cell.

2. (Amended) The method according to Claim 1, further characterized in that the markers are selected from the group consisting of [at least one of the following groups]: tumour suppressor genes, apoptosis genes, proliferation genes, repair genes and viral genes.

3. (Amended) The method according to Claim[s] 1 [and 2], characterized in that at least one of the [following] markers comprises [is present in the combination:] her2/neu, p16, p53, MN, mdm-2, bcl-2, EGF receptor, and specific DNA from the HPV subtypes 6, 11, 16, 18, 30, 31, 33, 35, 45, 51 and 52.

4. (Amended) The method according to one of Claim[s] 1 [- 3], wherein [characterized in that] the marker combinations comprise her2/neu with p16 or EGF-R with p16 or p53 with her2/neu or her2/neu with mdm-2 or bcl-2 with p16 or bcl-2 with her2/neu or p16 with p53 [are present].

5. (Amended) The method according to one of claim[s] 1 [- 4], further characterized in that 3 markers are detected.

6. (Amended) A kit for implementing the method according to [one of] Claim[s] 1 [- 5].

7. (Amended) The kit according to Claim 6, further characterized in that the reagents are antibodies or nucleic acids.

8. (Amended) The kit according to Claim[s] [6 and] 7, characterized in that the antibodies or nucleic acid probes are read directly or indirectly using fluorescent or chromogenic dye substances.

9. (Amended) The method according to [one of] Claim[s] 1 [- 8], characterized in that it enables abnormal cells to be detected in an automated manner, characterized in that at least two markers are detected and the signal intensities are combined and summated.

10. (Amended) The method according to Claim 9, characterized in that the automatic information processing is combined with a diagnostic expert system which enables the image information to be consolidated into a proposed diagnosis and, where appropriate, enables reflex testing to be carried out.

11. (Amended) The method [Entire process] according to Claim[s] 1 [- 10], wherein [characterized in that] the method comprises [process consists of] fully automatic sample preparation, sample staining, sample reading and information processing or subprocesses which comprise at least two of the given subprocesses.